Have Patent, Will Travel: Brand Firms Can File Infringement Suits Anywhere

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Executive Summary

Federal Circuit denies Mylan's bid to dismiss litigation in Delaware; PhRMA, BIO and Teva argued that brand manufacturers should be allowed to sue multiple generic manufacturers in a single forum.

Brand-name drug makers will be able to file patent infringement suits against generic manufacturers in whatever jurisdiction they wish, under a decision by the U.S. Court of Appeals for the Federal Circuit.

In a March 18 decision, the Federal Circuit denied **Mylan Pharmaceuticals Inc.**'s attempt to dismiss litigation brought in the District of Delaware on the grounds that the court did not have personal jurisdiction over Mylan. A ruling in favor of Mylan would have enabled the generic manufacturer to require that it be sued on its home turf in West Virginia and it would have prevented brand-name companies from bringing consolidated actions against generic defendants.

The appeals court found that Mylan's filing of ANDAs is sufficient grounds for an infringement suit to be brought against the company in Delaware since Mylan would be marketing its generics in the state once they are approved. Given the close ties between the filing of an ANDA and future marketing, the court said there is sufficient minimum contact with the state for the court to have specific personal jurisdiction.

Acorda Therapeutics Inc. sued Mylan for infringement of patents on its multiple sclerosis drug *Ampyra* (dalfampridine), and **AstraZeneca AB** brought suit against Mylan for infringing patents on its diabetes drugs *Onglyza* (saxagliptin) and

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Kombiglyze (saxagliptin/metformin) after Mylan filed ANDAs for generic versions of the drugs. Both suits were filed in the District of Delaware.

The case was closely watched by industry. The Pharmaceutical Research and Manufacturers of America, Biotechnology Innovation Organization, and **Teva Pharmaceuticals USA Inc.** submitted briefs in support of Acorda and AstraZeneca.

Jurisdictional Disputes, Protective Suits May Decline

Mylan filed motions to dismiss the complaints on the grounds that the state of Delaware, and therefore the district court, could not exercise personal jurisdiction over Mylan in these cases under the Due Process Clause of the Fourteenth Amendment. The district judges in both cases denied Mylan's motions to dismiss the complaints and the Federal Circuit affirmed.

"Mylan does not show that a state is forbidden to exercise its judicial power to prevent a defendant's planned future conduct in the state, but must wait until the conduct occurs," the Federal Circuit stated. "As long as the connection to the planned acts is close enough, the subject of such actions really fits the terms of the minimum-contacts standard – conduct purposefully directed at the state that gives rise and is related to the suit."

The court said specific personal jurisdiction can be overcome if the defendant shows that other factors, such as the burden on the defendant, would make the jurisdiction unreasonable. But it said Mylan could not show other factors weigh against litigating the cases in Delaware. The court noted that Mylan has litigated many ANDA lawsuits in Delaware, including some that it initiated.

There are two forms of personal jurisdiction, which is a court's authority over the parties to a suit. Specific personal jurisdiction requires a relationship between the claim and the forum, i.e., actions must take place in the state or be directed to the state. General personal jurisdiction means a defendant can be sued in a forum for any action, whether or not it takes place in the state.

Bruce Wexler, a partner at Paul Hastings, said there were not many jurisdictional disputes before the Supreme Court's 2014 decision in Daimler AG v. Bauman, which made it more difficult to establish general jurisdiction. Since then, he said, there has been an uptick.

The Federal Circuit's decision means innovator pharmaceutical companies can sue in a forum of their choice and with more efficiency and won't "waste time and energy with jurisdictional disputes," Wexler said.

In addition, he said the ruling may curtail protective suits, whereby patent holders file the identical suit in another district court to hedge against jurisdictional challenges.

PhRMA And Teva Advocate Single Forum

Mylan could not be reached for comment on whether it intends to seek a rehearing by the full court or appeal the decision to the Supreme Court.

In a sign of how important the case is, both sides hired former Solicitor Generals. Theodore Olson, a partner at Gibson, Dunn & Crutcher argued for Acorda and AstraZeneca, and Paul Clement, a partner at Bancroft, argued for Mylan.

Dennis Crouch, a professor at the University of Missouri School of Law, said in a blog post that the hiring of these top Supreme Court lawyers means that the companies

are planning to take the case up to the Supreme Court if allowed to do so.

PhRMA said in its brief that it is understandable that defendants like Mylan would prefer to have the court hold that they can be sued only in their home forum. But it stated that this would lead to absurd results.

"If district courts are effectively required to find that jurisdiction to hear an ANDA suit exists only in the defendant's home forum, patent owners will be for forced to litigate … infringement suits in a number of different districts spread out across the country rather than concentrating their litigation in a single forum," the association stated.

Teva echoed this concern in its brief. "Allowing the brand manufacturer to sue multiple generic defendants in a single forum where they plan to sell, rather than in their scattered home jurisdictions, helps to facilitate consolidation and, thus, the prompt and effective adjudication of patent challenges," the company said.

Teva noted that it sued Mylan in Delaware District Court after Mylan filed an ANDA for a generic version of Teva's *Copaxone* (glatiramer) 40 mg/ML injection. Mylan filed a motion to dismiss the complaint for lack of personal jurisdiction and the district court denied the motion pending the resolution of the case before the Federal Circuit.

Mylan has filed similar motions in several other cases.

Circuit Judge Kathleen O'Malley issued a concurring opinion saying that she agreed with the decision but that it should have been reached by addressing the question of general jurisdiction rather than specific jurisdiction.

The court found specific jurisdiction because Mylan's ANDA filings indicate plans to begin marketing the proposed generic drugs in Delaware. O'Malley said that Mylan's expression of interest in marketing its product on a nationwide basis, including Delaware, "reinforces the *immediate* harm caused by the ANDA filing, regardless of whether such marketing ever occurs."